

Lesson learned from Investigators of Clinical Trials to Identify Therapeutics for COVID-19 : A Qualitative Study

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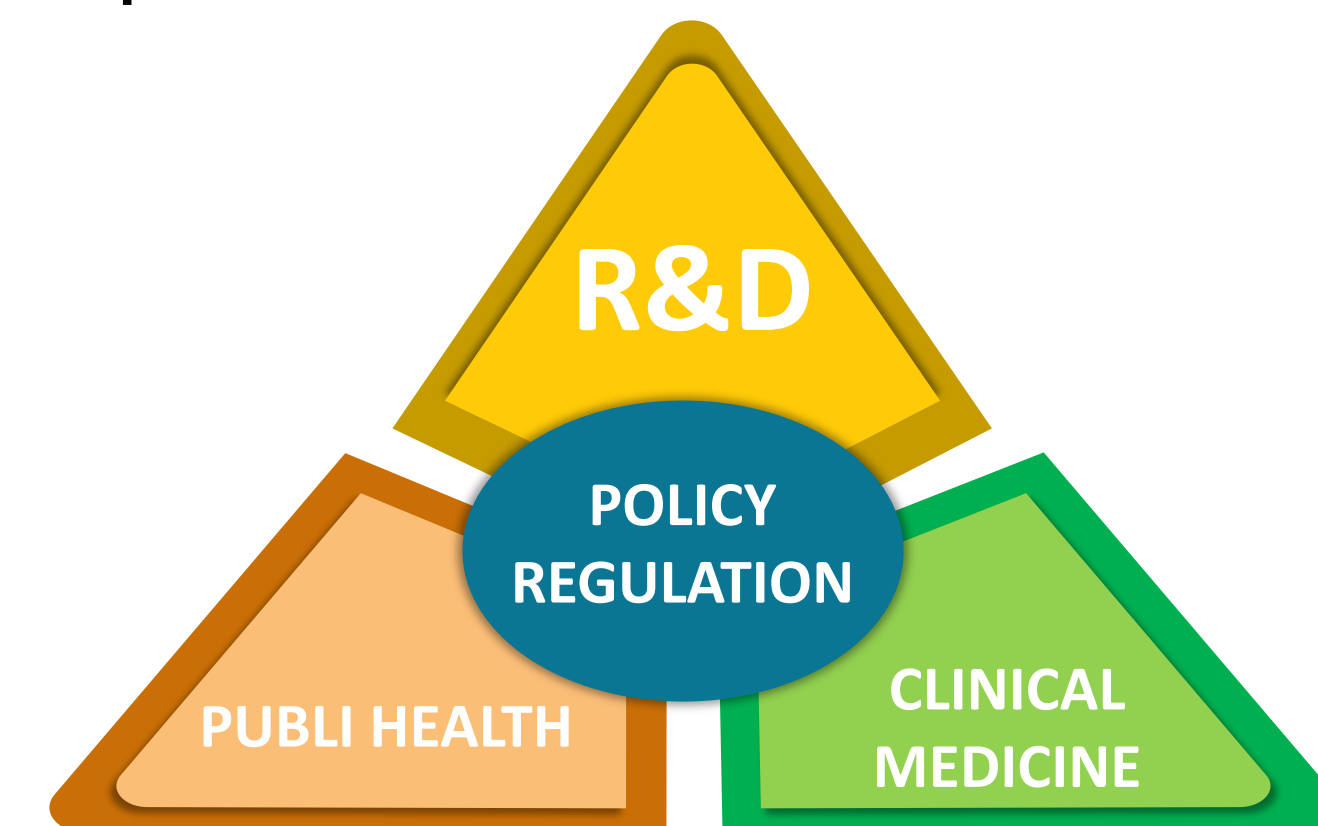


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The Problem

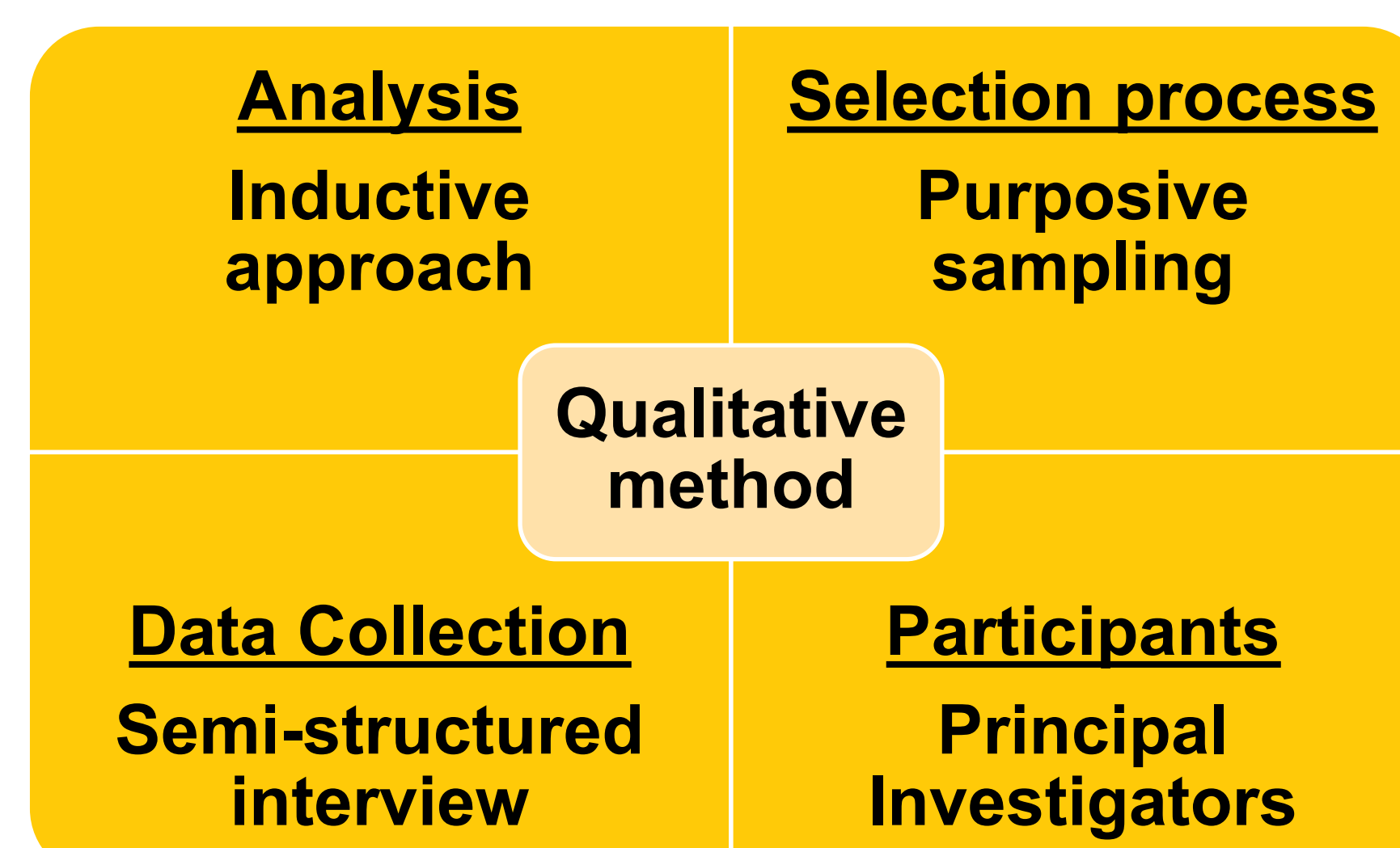
- Japan has limited contribution to developing therapeutics for COVID-19
- It is unknown how each stakeholder played a role during COVID-19 pandemic
- Comprehensive survey of stakeholders reg. clinical trials is essential to prepare for next pandemic



Objectives

To better understand the perspective of clinical investigators on facilitating and obstructive factors to conduct clinical trials on COVID-19 therapeutics in Japan

Methods



Results

Facilitators

The support from regulatory agencies, high enrollment rate of participants, organizational commitment to implement clinical trials and presence of clinical providers who are enthusiastic to develop evidence through clinical trials



Obstacles

Obstacles in system level

Limitation due to regulatory framework

- Unique Japanese regulatory system regarding clinical trials to develop therapeutics
- Non-transparent cost sharing process when conducting clinical trials
- Insufficient criteria to select facilities for clinical trials
- Complex process that put burden on investigators
- Lack of longitudinal and sustainable funding mechanisms for clinical trials during pandemics
- Government's lack of vision at the early stage of pandemic

Lack of clinical trial platform

- Needs to recruit patients by each trial
- Difficulty in finding facilities to enroll patients
- Lack of clinical networks to expand enrollment of patients

Lack of awareness of the public

- Patient's preference for passive engagement in medical decision
- Health literacy

Obstacles in clinical level

Limited capacity of health care facility to conduct clinical trials

- No systematic and organizational infrastructure to implement clinical trials
- No reserve for clinical trials during pandemic

Lack of experts and human resources

- Few researchers for clinical trials in infectious diseases field
- Factors associated with lowering motivation for researchers
- Researchers require ability to manage multidisciplinary team
- Cultivate interests in clinical trials among clinicians

Difficulty in finding trial participants

- The number of cases in community parallels the number of participants in trials.
- Difficulty in identifying potential facilities that could participate in clinical trials

Conclusions

- Investigators recognized both obstacles and facilitators
- System level obstacles led to the obstacles in clinical level
- Healthcare policy needs to respond to lessons learned from COVID-19 and prepare for the future health emergencies due to infectious diseases

Further info.

Comprehensive survey/interview are underway jointly with REMAP-CAP Japan



1. Regulatory agencies
2. Patients who joined clinical trial for therapeutic trial
3. Academia, academic research organization
4. Pharma
5. Public health/surveillance organization

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